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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/725,935 | 12/03/2003 | Martin K. Safo | 02940228AA | 4484 |

30743 7590 11/10/2005

WHITHAM, CURTIS & CHRISTOFFERSON, P.C.
11491 SUNSET HILLS ROAD
SUITE 340
RESTON, VA 20190

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| EXAMINER |
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SOLOLA, TAOFIQ A

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| ART UNIT | PAPER NUMBER |
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1626

DATE MAILED: 11/10/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/725,935

Applicant(s)

SAFO ET AL.

Examiner

Taofiq A. Solola

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 23 September 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 19-29 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 19-29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on 19 May 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>3</u> . | 6) <input type="checkbox"/> Other: _____ |

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Claims 19-29 are pending in this application.

Claims 1-18 are cancelled.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 19 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The phraseology "an aldehyde protecting thiozolidine group", line 5, is not supported by the specification. Throughout the specification and in claims 23-25, the representative structures described by the phraseology have no aldehyde and therefore there could not have been "an aldehyde protecting thiozolidine group." In fact in the representative structures, aldehyde is replaced and not protected by thiozolidine group. Therefore, the specification lacks adequate support for claim 19 as written. Appropriate correction is required.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 23-25, 27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims improperly depend from claim 19 for not being within the scope of claim 19. While the structure in claim 19 must have an aldehyde at position R1 protected by a thiozolidine

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group, there is no such in the structures of claims 23-25 and 27. Therefore, the claims are indefinite. Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 19-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Zaugg et al., J. Biol. Chem. (1977), Vol. 252, No. 23, pages 8542-8548.

Zaugg et al., disclose that aromatic aldehydes, e.g. furfural (compound 25), are useful for inhibiting hemoglobin sickling.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 21-22, 25-26, 28-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zaugg et al., J. Biol. Chem. (1977), Vol. 252, No. 23, pages 8542-8548.

Applicant claims a method of using various aromatic aldehydes for treating sickle cell disease. In claim 21, the ring is thiophen; in claims 22, 25-26, the ring is furfural having

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hydroxylalkyl substituent at position R4 and in claims 28-29 the ring is furfural having alkyl at position R4. All the rings have aldehyde substituent at position R1.

Determination of the scope and content of the prior art (MPEP §2141.01)

Zaugg et al., teach that aromatic aldehydes, e.g. furfural (compound 25), are useful for inhibiting hemoglobin sickling. The aromatic aldehydes are 5- and 6-atom rings, the rings have various substituents at different positions, some rings are none-heterocyclic while furfural is heterocyclic and all the rings have aldehyde substituent at position R1. Zaugg et al., teach that the aldehyde substituent forms Schiff base (imine) linkage with amino group of intracellular hemoglobins. Hence, the antisickling effect.

Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)

The difference between the instant invention and that of Zaugg et al., is that Applicant claims specific aromatic aldehydes having S instead of O as ring heteroatom, alkyl or hydroxylalkyl at position R4 instead of H as in the compounds of Zaugg et al.

Finding of prima facie obviousness---rational and motivation (MPEP §2142.2413)

However, H and alkyl are art recognized equivalents. *In re Lincoln*, 126 USPQ 477, 53 USPQ 40 (CCPA, 1942); *In re Druey*, 319 F.2d 237, 138 USPQ 39 (CCPA, 1963); *In re Lohr*, 317 F.2d 388, 137 USPQ 548 (CCPA, 1963); *In re Hoehsema*, 399 F.2d 269, 158 USPQ 598 (CCPA, 1968); *In re Wood*, 582 F.2d 638, 199 USPQ 137 (CCPA, 1978); *In re Hoke*, 560 F.2d 436, 195 USPQ 148 (CCPA, 1977); *Ex parte Fauque*, 121 USPQ 425 (POBA, 1954); *Ex parte Henkel*, 130 USPQ 474, (POBA, 1960).

The compounds of claims 21-22, 25-26 have aldehyde substituent at position R1. One of ordinary skill in the art would have been motivated to confirm if in fact the compounds are useful for treating sickle cell disease. That is, applicant merely did what is expected.

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Therefore, the instant invention is prima facie obvious from the teaching of Zaugg et al. One of ordinary skill in the art would have known to substitute alkyl for H in the compound of Zaugg et al., and claim the method of using aromatic aldehydes for treating sickle cell disease at the time the invention was made. The motivation is from knowing that H and alkyl are equivalents, and from the teaching of Zaugg et al., that aromatic aldehydes are useful for treating sickle cell disease.

Telephone Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Taofiq A. Solola, PhD. JD., whose telephone number is (571) 272-0709.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Joseph McKane, can be reached on (571) 272-0699. The fax phone number for this Group is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.


TAOFIQ SOLOLA
PRIMARY EXAMINER
Group 1626

November 2, 2005